UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/654,948	09/01/2000	J. Leighton Read	2719.2003-000	7877

42145 7590 07/08/2005

FISH & NEAVE IP GROUP
ROPES & GRAY
ONE INTERNATIONAL PLACE
BOSTON, MA 02110

EXAMINER	
PONNALURI, PADMASHRI	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 07/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/654,948	READ ET AL.	
	Examiner	Art Unit	
	Padmashri Ponnaluri	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/11/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *172-214* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *172-214* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/9/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/11/05 has been entered.

2. The amendment and response filed on 4/11/05 has been fully considered and entered into the application.

3. New claims 210-214 have been added by the amendment filed on 4/11/05. Claims 172-214 are currently pending and are being examined in this application.

4. The references filed in the Information Disclosure Statement filed on 4/11/05 have been considered.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 172-184, 183, 186, 190-192, 210-214 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is Written Description Rejection.

The instant claims briefly recite a method of synthesizing a polypeptide array, by Contacting a surface of substrate with a first protected amino acid such that the amino acid couples to the functional group; contacting with a second protected amino acid, such that the amino acid couples to the functional group; repeating the contacting and coupling steps until a positionally defined array of peptides is formed.

Claim173 recites 'without physical segregation of said surface.'

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.

The written description requirement can be met by 'showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics.... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure or some combination of such characteristics.' *Enzo Biochem,Inc. v. Gen-Probe Inc., 296 F 3d. 1316, 1324, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002).*

Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.

The specification description is directed to the use of a mask and photo lithographic techniques in the methods of making arrays of chemical compounds such as peptides or oligonucleotoides; which clearly do not provide an adequate representation regarding the open ended method of synthesizing a positionally defined polypeptide array of the instant claims. The use of photolithographic technique is critical or essential to practice the instant invention of positionally defined polypeptide array.

The specification has a list of reagents which could be used in solid phase chemical synthesis, however, have not shown that the reagents are used or any advantages of the use of the reagents in the claimed method. Further the specification specifically discloses the advantages of the use of the photolithographic technique by reciting in page 10, 'by using lithographic techniques disclosed herein, it is possible to direct light to relatively small and precisely known location on the substrate. It is therefore, possible to synthesize polymers of a known chemical sequence at known locations on the substrate.'

The specification disclosure does not disclose the use of techniques other than photolithography in the synthesis of positionally defined polypeptide array of the instant claim method. At the time the application was filed the methods of making polypeptides arrays were considered as unpredictable art. In emerging technologies or in unpredictable art such as 'polypeptide array synthesis', the disclosure of a single species is not representative of the genus. Thus, the claimed invention lacks written description by disclosing only the 'photolithographic methods in polypeptide array synthesis as claimed.' Further, the specification discloses the use of a mask to spatially define discrete areas of the solid support in the synthesis of positionally

defined polypeptide arrays. The specification has not disclosed the methods of polypeptide array synthesis without physical segregation of the solid support.

With regard to the description requirement, applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a Awritten description of an invention involving a chemical genus, like a description of a chemical species, >requires a precise definition, such as by structure, formula [or] chemical name of the claimed subject matter sufficient to distinguish it from other materials. *University of California v. Eli Lilly and Co.,* 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel,* 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

"Regardless whether a compound is claimed per se or a method is claimed that entails the use of the compound, the inventor can not lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods." *Cf. University of Rochester v. G.D. Searle & Co., Inc., Monsanto Company, Pharmacia Corporation, and Pfizer Inc. No. 03-1304, 2004 WL 260813 (fed. Cir., Feb. 13, 2004).*

These holdings would be deemed to be applicable to any compound or methods of making the compounds or arrays; which requires a representative sample of methods of making the compounds and/or a showing of sufficient identifying characteristics to demonstrate possession of the claimed generic(s).

At the time the application was filed the methods of making polypeptides arrays were considered as unpredictable art. In emerging technologies or in unpredictable art such as

'positionally defined polypeptide array synthesis', the disclosure of a single species (disclosure of the use of Photolithography and mask in the array synthesis) is not representative of the genus (polypeptide array synthesis using any known energy sources, and technologies). Thus, the claimed invention lacks written description by disclosing only the 'photolithographic methods in polypeptide array synthesis as claimed.'

Additionally, the narrow scope of examples directed to photolithography technique in making arrays (species) are clearly not representative of the scope of the claimed method of synthesizing array of polypeptides (genus).

7. Claims 172-184, 183, 186, 190-192, 210-214 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of photo lithographic techniques in the polypeptide array synthesis, does not reasonably provide enablement for other techniques (such as chemical, magnetic in the positionally defined polypeptide array). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims briefly recite a method of synthesizing a polypeptide array, wherein said array comprises at least two different polypeptides immobilized on a substrate, comprising: a) contacting said surface with a first protected amino acid; b) contacting the said surface with a second protected amino acid; and c) repeating the above steps until at least two different polypeptides are formed at known location on said substrate surface.

The specification disclosure does not have a sufficient enabling disclosure for the use of chemical or thermal or magnetic techniques to remove the protecting groups from the compounds so that activated region on the surface is formed.

The factors to be considered in a determination of undue experimentation are disclosed in *re Wands* (U. S. P. Q. 2d 1400: CAFC 1988) which include: the quantity of experimentation necessary; the amount of direction or guidance presented; the presence or absence of working examples; the nature of the invention; the state of the prior art; the predictability of the art; and the breadth of the claims.

A number of factors would prevent one of ordinary skill in the art from practicing (making and using) the invention without undue experimentation, which are summarized as follows:

a. The specification fails to give adequate direction and guidance as to the means of synthesizing arrays of polypeptides using techniques other than photolithographic technique. The specification discloses selective deprotection and/or activation with photolithography using a mask (physical segregation). The specification discloses that the photolithographic technique makes it possible to direct light to relatively small and precisely known location on the substrate using a mask and photolithography techniques. The specification has neither disclosed nor given guidance on how to use different kinds of energy (i.e., energy sources other than light, such as magnetic, electrodes) in selectively protecting or de-protecting the amino acids of discrete locations of the substrate.

b. The working examples are limited and are directed to the use of photolithographic technique in making arrays of polypeptides or nucleotides.

c. The breadth of the claims are open-ended regarding the 'selectively activating regions of surface', and the use of different energy sources other than light energy in the method of making the arrays.

d. The state of the prior art at the time the invention was made is such that synthesis of array of compounds on a substrate, by selective protecting and deprotecting (i.e., using chemical or magnetic methods) in general are known to be difficult or unknown. The polypeptide array synthesis on a solid support by selectively activating selective areas of the surface is unpredictable. The specification has not taught what kind of physical barriers can be used with different energies, and the types of protecting and de-protecting groups are useful with different types of energies, such that a spatially defined polypeptide array can be synthesized. And further, the specification has not taught how the spatially defined polypeptide array is synthesized without physical barriers. The specification has not taught the solid supports which can be spatially defined without physical barriers, or the use of such physical supports in the synthesis of polypeptide array.

e. The art is inherently unpredictable because organic synthesis of peptide array on a substrate and selective protecting and or deprotecting of compounds using chemical or the thermal methods is not possible without using other methods (such as masking or using barriers).

f. The level of skill would be high, most likely at the Ph.D. level. However, from the specification disclosure, a person skilled in the art would require undue amount of experimentation to use other kinds of techniques in synthesis of spatially defined polypeptide array.

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, and the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 172-214 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,506,558 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference claims are drawn to a method of forming a plurality of polypeptides or nucleic acids occupying known locations on a substrate, and the reference claim is drawn to both nucleic acid array and polypeptide array. Further the reference does not specifically recite 'array', however "a plurality of polypeptides or nucleic acids occupying known locations on a

substrate" reads on the array. The reference method steps are written differently, however the reference method steps are same in scope as the instant claim method steps. Thus, the claimed method is obvious over the reference method.

10. Claims 172-214 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-54 of U.S. Patent No. 6,379,895 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference claims are drawn to a binary synthesis method for synthesizing a plurality of polypeptides, and the instant claims broadly recite a method of preparing an array of peptides and would read on the reference claims.

Response to Arguments

11. *Applicant's arguments filed on 4/11/05, regarding the written description rejection have been fully considered but they are not persuasive.*

Applicants assert that the 'chemistry of reacting one amino acid with another has been well developed since the 1960s with the advent of Merrifield Synthesis, and also means of removing protecting groups was also developed.'

Applicant's assertions have been fully considered and are not persuasive. Examiner agrees that 'solid phase synthesis of peptides' is well known in the art at the time the invention was made. However, the instant claimed method is not drawn to 'solid phase synthesis of a single peptide on the solid support' as in applicant's assertions. The instant claimed method is drawn to synthesis of positionally defined polypeptide array, in which protected amino acids are coupled to selected regions (positionally defined region) of the solid support. Thus, the instant claimed method is distinct from the Merrifield Synthesis methods.

Applicants further argue that the present application methods that selectively react amino acids to form different polypeptides in spatially discrete locations on a substrate. The knowledge in the art coupled with the present application teachings were sufficient to teach one of skill in the art to make and use the claimed subject matter.

Applicant's arguments have been considered and are not persuasive. Because the instant specification only teaches the use of photolithography to react amino acids at spatially defined discrete locations on a substrate. The specification has not taught how to use other methods such as chemical or magnetic, in the method of synthesis of polypeptide array in which protected amino acids are reacted at positionally defined discrete location of the substrate.

Applicants argue that 'the preparation of polypeptide arrays according to the present claims was novel, and non-obvious as of the effective filing date, the chemistry was not unpredictable in view of teachings of the specification and the knowledge of the skilled artisan.'

Applicant's arguments have been considered, however applicants have not shown or given guidance on how the spatially defined polypeptide arrays are synthesized using techniques other than the photolithography. Applicants have not provided any references known at the time of the invention was filed, which teach the use of different energy sources (other than light as energy source) in synthesis of polypeptides, and references teaching methods of spatially defined array synthesis i.e., the use of other energy sources such as chemical, magnetic filed, heat or microelectrodes in selectively protecting and deprotecting amino acids, such that the teachings would be useful in view of the specification teachings, a polypeptide array of the instant claimed method can be prepared. Further, the instant claims 173, 211 recite 'without physical segregation of said surface.' However, the specification has not disclosed the peptide array

synthesis methods without the physical segregation and use of different kinds of energy in the protecting and de-protecting amino acids at discrete selected regions of the support. The specification has not taught how to protect and de-protect selected amino acids at selected discrete regions of the solid support using different energy sources.

Applicants assert that the difference between the array preparation and conventional solid phase synthesis is, at least, that the areas for reaction are controlled in array preparation so that different polypeptides are formed in different areas.

Applicants assertions have been fully considered and are not persuasive, because the solid phase synthesis of peptides is well known in the art, however, spatially defined polypeptide array synthesis is not known at the time the invention was made. The reactions would be different because depending on the energy source used different protecting and deprotecting reagents is required, and further to prepare spatially addressable polypeptide array requires other techniques such as lithography such that protecting or de-protecting of amino acids at defined positions is possible. The specification has neither disclosed nor given direction on how to use different kinds of energy to protect or de-protect amino acids at selected regions of the surface and further without physical segregation of the solid support.

Applicants ague that there is no requirement that the application reiterate the details of methods that were well known as of the filing date, and the specification should be held to fulfill the written description requirement. Applicants arguments are not persuasive, because the methods of selectively protecting and de-protecting using different energy sources is not well known in the art at the time the invention has filed. Applicants have not provided any teachings in which different peptides (more than one peptide on a single support) synthesis methods in

which the amino acids are selectively protected and deprotected at the selected regions of the solid support.

The specification only discloses attaching amino acids to certain defined regions of a substrate using light energy and a mask (a physical barrier), such that different polypeptides are formed at spatially defined positions of solid support. The array technology or methods of preparing spatially defined polypeptide array technology was not well known at the time the invention, such that a person of ordinary skill in the art would know how to use different energy sources in synthesis of spatially defined polypeptide array.

Applicants' argue that the specification discloses different energy sources, and one of ordinary skill in the are would have known suitable protecting groups for use in conjunction with the energy sources, and barriers for energy source were generally well known.

Applicant's arguments have been considered and are not persuasive, because the specification has neither taught nor given guidance on how to use different energy sources, the suitable protecting groups in synthesis of spatially defined polypeptide array.

The means of protecting and deprotecting reagents listed in the specification were not shown to be use in the claimed method of 'selectively protection or deprotection of reagents on defined locations of the substrate.' The specification has a list of reagents which could be used in solid phase chemical synthesis, however, have not shown that the reagents are used or any advantages of the use of the reagents in the claimed method. Depending on the energy source, the protecting groups used and methods of peptide synthesis would differ. And it was not well known in the art at the time of the invention how to synthesize at least two different polypeptides

on the solid support using different energy sources. Thus, the prior art methods would not result in array of polypeptides.

For inventions in emerging and unpredictable technologies, or for inventions characterized by factors not reasonably predictable, which are known to one of ordinary skill in the art, more evidence is required to show possession. At the time the application was filed the methods of making polypeptides arrays were considered as unpredictable art. In emerging technologies or in unpredictable art such as 'polypeptide array synthesis', the disclosure of a single species (photolithography methods) is not representative of the genus. Thus, the claimed invention lacks written description by disclosing only the photolithographic methods in polypeptide array synthesis.

12. Applicant's arguments filed on 4/11/05, regarding lack of scope enablement rejection have been fully considered but they are not persuasive.

Applicants assert that the enablement requirement is met if the description enables any mode of making and using the claimed invention.

Applicant's assertions have been considered, and is not persuasive because the rejection was made under 'scope enablement', and the examiner agrees that the specification is enabling for photolithographic techniques. However, the rejection states that the specification has not disclosed the techniques other than photolithographic techniques in synthesis of spatially defined polypeptide array.

Applicants argue that the examiner has not considered that the specification discloses other means of selecting a relatively small and precisely known location on a substrate for

contact with a reagent. For example, the physically divided or etched substrate having surface features such as trenches, v-grooves and mesa structures allow one to direct a solvent to specific locations on a substrate and then selectively protect and deprotect these specific locations.

Applicants arguments and assertions have been considered and are not persuasive because, the instant claim is not limited to the use of physical barriers, for example see claim 173, which recites 'without physical barriers.' Thus, the specification has neither taught nor given guidance on how to use different energy sources in synthesis of spatially defined polypeptide array without physical barriers. And further, regarding applicants arguments that 'the specification discloses physically divided or etched surface,' are not persuasive since the specification has not taught how to direct these specific energies (such as magnetic energy) to a specific location of the support and how the magnetic energy is used in protecting and de-protecting the amino acids at specific location of the solid support. And further the 'trenches or v-grooves' limitations would only be useful in maintaining the reagents in certain regions, and not related to the instant claimed method selectively activating regions of the solid surface and synthesis of array or polypeptides as claimed.

Applicants arguments regarding the 'direction and guidance' in the specification have been considered, and are not persuasive. Applicants argue that 'lithographic techniques' in general are clearly enabled by the specification. And it is apparent from the specification that the photolithography examples are analogous to the methods that would be used with another lithographic techniques. The only requirement is that the mask used be functionally impermeable to the type of radiation being employed.

The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. If little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling. In the instant case, the 'polypeptide array synthesis on a solid support by selectively activating selective areas of the surface' is unpredictable. A person skilled in the art cannot readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is lack of predictability in the art. In re Marzocchi, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971), stated: [I]n the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles. Most often, additional factors, such as the teachings in pertinent references, will be available to substantiate any doubts that the asserted scope of objective enablement is in fact commensurate with the scope of protection sought and to support any demands based thereon for proof. [Footnote omitted.]

Applicants argue that the working examples of the photolithography relate to one preferred embodiment, and one of ordinary skill in the art would have immediately recognized

that other techniques for activating a region of substrate proceed analogously. Examiner agrees that the 'photolithographic techniques' are analogous to the other lithographic methods, however the mask used has to impermeable to the radiation employed. The specification has not taught the types of masks that can be used with different radiations, and the instant claims are not limited to the use of lithographic techniques only.

Applicants assert that the 'applicants were the first to use selective protection/de-protection to make an array of polymers, the concept of generalized protection/de-protection chemistry involved in these selective regions is the same as in the conventional techniques.'

Applicant's assertions have been considered and are not persuasive. Even though the chemistry involved in the selective regions is same as in conventional techniques, the instant claimed method of synthesizing positionally defined at least different polypeptides on a single solid support or simultaneous synthesis of more than one polypeptide on a same solid support is not conventional chemistry.

Applicants argue that the number of different polypeptides formed per unit area is irrelevant in the independent claims 193, 210. This argument is not persuasive, since the rejection is not pertinent to these claims.

Applicants assert that as shown in Exhibit A, there were 300 publications on solid phase synthesis as the effective filing date, such that a large body of knowledge on the subject was available to one of skill in the art.

Applicants assertions have been fully considered and are not persuasive, since the instant claimed method is not drawn to specifically a solid phase synthesis of a single peptide on a solid support. The instant claimed method is drawn to method synthesizing polypeptide array, wherein

said array comprises at least two different polypeptides at positionally defined locations of a single solid support. None of the references in the exhibit A, show simultaneous synthesis of more than one polypeptide sequences on a solid support, or the use of different types of energies in solid phase polypeptide array synthesis or different types of physical barriers useful with different kinds of energy used. Thus, the chemistry is considered as unpredictable at the time the invention was made.

And applicants arguments regarding the protecting groups in Exhibit B has been considered and is not persuasive because, a) the exhibit B seem to be after effective filing date of the claimed invention; b) the specification has neither taught nor given guidance on how to use these well known protecting groups (i.e., electrolytically-removable protecting groups, and different types of energy (i.e., microelectrodes) in the spatially defined polypeptide array of the instant claims. Thus, for the reasons of record the rejections have been maintained.

13. Applicant's response filed on 4/11/05 regarding the obviousness type double patenting rejections over US Patent 6,379,895 and US Patent 6,506,558, have been fully considered but they are not persuasive. The rejections of record have been maintained, and would be withdrawn upon filing of terminal disclaimer and entered into the application.

Conclusion

14. The following is a statement of reasons for the indication of allowable subject matter: The claimed method of synthesizing polypeptide array (independent claim 193) is allowable upon filing of terminal disclaimers to overcome the obviousness-type double patenting rejections of record.

15. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PADMASHRI PONNALURI
PRIMARY EXAMINER

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

06 July 2005